durability of plaque modification.
**Methods:** Patients with PAD underwent primary intervention with orbital technology followed by low pressure balloon. Lesion compliance markers, including maximum post-orbital balloon inflation pressures, inflation times, dissection rates and bail-out stent rates, were recorded. 12-month reintervention rates were also tracked.
**Results:** 46 patients (74% male, 71 yrs) with 57 fibrotic or calcified lesions. Patient demographics: diabetes (50%), renal disease (39.1%), CAD (67%), HTN (98%), hyperlipidemia (94%), Rutherford 3-5. Lesion locations: CFA (9%), SFA (56%), popliteal (19%) and tibial/peroneal (16%). Average pre-treatment stenosis was 89%. In 84% of cases, balloon inflation was utilized to achieve a mean residual stenosis of 10.5%. Mean maximum inflation pressure was 5.3 atms for a mean of 2.3 min. 1 dissection was reported. No bail-out stenting was required. 5 patients (10.9%) returned for re-treatment of the target lesion within the 12-month follow-up period.
**Conclusion:** In this study, the use of orbital technology modified lesion compliance in resistant plaques as demonstrated by low pressure and short duration post-orbital balloon inflations. Bail-out stenting was eliminated in this challenging patient population, and use of orbital technology resulted in durable long-term results with a low reintervention rate.

## TCT-577

### TEVAR in 2011: Worldwide Experience with a Conformable Graft. Does the Combination of Flexibility and Radial Strength Lead to Positive Outcomes in Thoracic Pathologies?

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**Background:** The anatomies of patients treated with TEVAR are as diverse as the pathologies that are being treated. Increased graft flexibility and conformability may contribute to a device's ability to adapt to these different anatomies and pathologies. We report the worldwide experience of the Valiant thoracic stent graft (Medtronic Vascular, Santa Rosa, Calif) in treatment across aortic pathologies.
**Methods:** Three major studies encompassing multiple pathologies are included in this analysis. VALOR II: a 160 patient prospective, nonrandomized, pivotal trial conducted in the US for the treatment of descending Thoracic Aneurysm (TAA) or degenerative disease, The Valiant Captivia Registry: a 100 patient post market registry conducted in Europe for the treatment of TAA or Aortic Dissection, and the VIRTUE Registry: a 100 patient prospective European registry for the treatment of acute, sub-acute, or chronic dissection.
**Results:** Thirty day mortality across all studies was 3.1-4%. The incidence of stroke at 30 days was 2.5 – 4% while spinal cord ischemia rates were less than 2%. There were no Type 1a endoleaks reported in the VIRTUE cohort and 1.5% incidence in the Valiant Captivia Registry group at 30 days. The incidence of Type 1 endoleak in the VALOR II cohort was 3% at 1 year. Across all patients, there was only 1 rupture and 1 conversion which were attributed to the same patient.
**Conclusion:** Early results from the VALOR II Study, the Valiant Captivia Registry, and the VIRTUE Registry demonstrate that the Valiant thoracic stent graft with its high conformability is effective in treating a variety of thoracic aortic pathologies including TAA and degenerative disease, as well as, acute, sub-acute, and chronic dissection.

## TCT-578

### Mechanical Thrombectomy in Treatment of Limb Ischemia: Interim Results of a Prospective Multi-Center Registry

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**Background:** To report registry data in which limb ischemia patients were treated with mechanical thrombectomy.
**Methods:** A two-phase ongoing prospective registry of the MEDRAD Angiojet catheter used in the treatment of acute and chronic limb ischemia was examined. Electronic data capture case report forms were completed by site staff collecting patient's history, procedural information including adjunctive treatments, outcomes and adverse events. Phase I patients were followed to 3 months post procedure while the ongoing phase II patients will be followed for 12 months.
**Results:** Currently 271 patient with acute (200/271; 74%) and chronic (71/271; 26%) limb ischemia at 42 centers have been treated (160 male and 111 female, mean age 66; range 21 to 96 years). All patients were treated with the Angiojet catheter, with 63% receiving lytic delivery by the AngioJet. CDT occurred in 45%. Full patency was achieved in 82% with a statistically significant improvement in ABIs ($p<0.0001$). Initial hospitalization AEs included: bleeding requiring transfusions 10/271 (4%), bypass surgery (11/271 (4%) and amputation 9/271 (3%). Of the 80% (218/271) with 3 month follow ups, 7/271 (3%) reported bypass surgery and another 6/271 (6%) had an amputation. The physical and mental QOL scores improved from baseline 37% and 11%, respectively. A 93% (124/133) limb salvage rate was reported for the acute limb ischemia patients with baseline Rutherford classifications of IIa, IIb and III.
**Conclusion:** Mechanical thrombectomy combined with adjunctive treatments is an effective and safe strategy for limb ischemia.

## TCT-579

### A New concept of Stent:the Multilayer Stent.First Human Study in Peripheral Aneurysms

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**Background:** Arterial aneurysms are traditionally treated surgically, but more and more by interventional procedures using covered stents Endografts or coils with a high technical success rate, but some problems are not solved like protection of aneurysm rupture, endoleaks, stent thrombosis. We developed a new concept of stent, the Multilayer stent (M.S) to treat aneurysms and try to avoid some drawbacks encountered with endografts.
**Methods:** This M.S is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest tests in vitro (theorical simulation, computerized Fluid dynamics, Molecular Modelization) and in vivo tests demonstrate that this MS reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this M.S preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels …)
**Results:** 32 peripheral aneurysms (iliac:20, femoral:1, popliteal:4, renal:6, mesenteric:1) were treated with the M.S, (male:25, mean age 61+/-8y) (42 stents Ø 5 to 14mm; length 40 to 100 mm) were implanted to treat these aneurysms, by femoral approach. Technical success in all patients. No complications. All aneurysms thrombosed with diameter reduction in some patients. 6 month to 30 month follow up will be presented and we will discuss the time needed to achieve exclusion and the factors influencing this exclusion. Allthe side branches remained patent.
**Conclusion:** A new concept of stent,is developed to treat aneurysm. It opens a new approach to treat peripheral aneurysms avoiding most of the complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

## TCT-580

### Clinical Evaluation of the IN.PACT Drug-eluting Balloon for Treatment of Femoro-popliteal Arterial Disease: Twelve Month Results from a Multicenter Italian Registry

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**Background:** Conventional balloon angioplasty in Superficial femoral and popliteal artery territories is associated with a high restenosis rates 12 months post-procedure. Recent clinical data have suggested that use of DEBs may substantially reduce restenosis. The impact of InPact Admiral(Medtronic Invatec, Roncadelle, Italy)DEB use on provisional stenting and 12 month clinical outcomes in routine clinical practice is described.
**Methods:** This prospective, observational registry enrolled patients with Rutherford class 2, 3, or 4 femoropoliteal arterial disease with reference vessel diameter of 3 to 7 mm and lesion or occlusion length ≤15 cm. Endpoints included restenosis rate, target lesion revascularization (TLR), and change in Rutherford class and ankle-brachial index (ABI). Walking capacity and quality of life (QOL) were also assessed
**Results:** At 12 months follow up, 105 patients (114 lesions) were evaluable. Baseline ABI was 0.56 ± 0.15. Baseline Rutherford classification was 26.7% for class 2, 64.8% for class 3, and 7.6% for class 4. Most lesions were located in the middle and distal superficial femoral artery (77.1%). The device was successfully deployed in all patients and only 12.3% of lesions required stenting. The rate of TLR was 8.7% at 12 months. QOL and functional status were substantially improved at all time points with 88% in Rutherford class 0 or 1, and a mean ABI of 0.81 ± 0.4 at 12 months

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